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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,646

10/27/2003

Anuja Patel

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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/694,646	<b>Applicant(s)</b> PATEL ET AL.	
	<b>Examiner</b> George P. Wyszomierski	<b>Art Unit</b> 1793	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/8/08 (RCE, Supplemental Decl.).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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1. The Request for Continued Examination (RCE) together with the proper fee, as well as the Supplemental Declaration of Craig Mar filed January 8, 2008 have been entered. Claims 1-23 are pending, with claims 15-21 withdrawn from consideration as directed to a non-elected invention.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beard (PG Pub. 2002/0005047).

Beard discloses Ni-Ti wires that are round in cross section, and have a composition, an  $A_f$  temperature, an ultimate tensile strength, and an elongation value as presently claimed. Note particularly Alloy #1 in paragraph [0007] of Beard. Thus, all physical aspects of the claimed invention appear to be fully disclosed (in the sense of 35 USC 102) by the Beard reference.

Beard does not specify that the material disclosed therein has undergone a cold work and anneal cycle, i.e. does not disclose the process steps recited in product-by-process terms in claim 1, and does not specify the conditions under which elongation and tensile strength were

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measured. However, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art. See *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524). Given that all composition, shape, and mechanical properties as claimed are present in the Beard materials, Applicant has not met this burden. With regard to the testing conditions, it is a reasonable assumption that testing was conducted under standard conditions by Beard, in the absence of any particular statement to the contrary. Thus, at a minimum, the claimed invention is held to have been obvious to one of ordinary skill in the art from the disclosure of Beard.

4. Claims 7, 8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beard.

With respect to claims 7 and 8, Alloy #1 of Beard is stated to contain <0.5% of C, O and Fe, which overlaps the amounts recited in the instant claims. Beard makes no mention of Cu, H, or “any other single trace element” and therefore the examiner assumes that the amounts of these elements in the Beard materials are negligible. Thus, no patentable distinction is seen between this aspect of the claimed invention and the Beard disclosure. With respect to claims 10-12 and 14, Beard does not specify the fatigue life value as presently claimed. However, Beard paragraph [0006] indicates that a typical fatigue life of the prior art materials is 10,000 cycles at 2% strain and 1,000,000 cycles at 0.5% strain; extrapolating these figures to the claimed conditions (0.75% strain), a value of >20,000 cycles for the prior art material appears reasonable. All statements made in item no. 4 supra with regard to product-by-process limitations apply equally as well in this instance. With respect to claim 13, Beard paragraph

[0019] discloses a size range in the prior art that includes the entire range as presently claimed. Thus, a prima facie case of obviousness is established between the disclosure of Beard and the presently claimed invention.

5. Claims 5, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beard, as above, in view of Ishibe et al. (U.S. Patent 5,230,348).

With respect to claim 5, while Beard does not appear to disclose any polygonal cross-section shaped materials, Beard paragraph [0011] states that the prior art materials may be formed into wires, rods or other shapes. Then, Ishibe Figures 5-9 indicate that polygonal cross-section materials were known to be equivalent in the art to the round cross-section materials disclosed by Beard, in the context of wires made from Ti-55.8%Ni alloy materials.

With respect to claims 22 and 23, Beard paragraph [0019] indicates that the prior art material may be made in the form of a plurality of braided wires, i.e. analogous to that defined in claim 23. Beard does not specify a "medical device for implantation" as required by the instant claims. However, it is unclear what particular physical form is implied by this limitation, as medical devices may be formed into a wide variety of shapes for diverse applications. Ishibe indicates that it was known in the art, at the time of the invention, to employ Ti-55.8%Ni wires (the same material as Beard) as guide wires for catheters, i.e. as medical devices. All statements made in item no. 4 supra with regard to product-by-process limitations and testing conditions apply equally as well in this instance.

Thus, the combined disclosures of Beard and Ishibe et al. would have taught the invention as presently claimed to one of ordinary skill in the art.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beard, alone or in view of either Iwai et al. (U.S. Patent 5,334,294) or Wang et al. (U.S. Patent 6,375,826).

Beard, discussed supra, does not appear to disclose a surface that is at least partially polished. However, the purpose of Beard is to make jewelry, and it is thus a reasonable assumption that one of skill in the art would want to have a polished, aesthetically pleasing surface in the materials of Beard. In any event, both Iwai and Wang indicate that it was known in the art, at the time of the invention, to electropolish wires made of Ni-Ti alloy, i.e. a material analogous to that of Beard. This allows one to achieve a very smooth surface of a desired shape. Thus, the disclosure of Beard, combined with that of Iwai et al. or Wang et al., would have taught the presently claimed invention to one of ordinary skill in the art.

7. In the Supplemental Declaration of Craig Mar, Declarant explains that the 16,560 cycles to failure of "standard nitinol wires" or of 22,760 cycles of an embodiment of the invention referred to in the present specification represent the fatigue lives of samples subject to a rotary beam test, whereas the fatigue life on the order of millions of hours discussed in the previous declaration filed November 21, 2007 represent a fatigue life based on a cyclical tensile fatigue test. The examiner accepts this explanation, but notes that it raises at least two points relative to patentability of the instant claims.

a) Precisely what is the difference between materials according to the invention and those of the prior art, i.e. do they have a longer cyclical tensile fatigue life or do they have a longer rotary beam fatigue life?

b) If the latter, the data presented is not commensurate in scope with the instant claims. Of the instant claims, only claims 10-14 have any limitation on fatigue life, and these claims state that the core has a fatigue life > approximately 20,000 mean cycles to failure. In the pages of Anuja Patel's notebook attached to the Supplemental Declaration, at least one set of results has an average time to failure significantly less than 20,000 cycles; note particularly the page dated 10-30-03.

Thus, Applicant has not overcome the prima facie case of obviousness with respect to Beard or with respect to Beard combined with Ishibe, Iwai, and/or Wang.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the central facsimile number, (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/George Wyszomierski/  
Primary Examiner  
Art Unit 1793

GPW  
March 10, 2008

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/694,646	PATEL ET AL.	
	Examiner	Art Unit	
	George P. Wyszomierski	1793	